

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Efficacy of a topical formulation of *Myrtus communis* L. for patients with chronic anal fissure

Protocol summary

Study aim

Efficacy of a topical formulation of *Myrtus communis* L. for patients with chronic anal Fissure

Design

Double blind, randomised, parallel groups, controlled clinical trial. The number of patients is 60.

Settings and conduct

The Patients that are diagnosed as chronic anal Fissure and have condition of entrance to the study will be assigned accidentally to one of the arm studies. The topical formulation of *Myrtus communis* L. or diltiazem are prescribed 3 times a day in 1.5 cm for the anal region after washing by warm water. At most 2 gr Acetaminophen is prescribed to relieve the pain during the first week of study. Also, it is recommended to observe proper nutrition habits. Then the change in the evaluated index is registered by calling every week and in presence every two weeks. The time of study is 4 weeks and the place is Hamze surgical Clinic.

Participants/Inclusion and exclusion criteria

The main inclusion criteria: age 18 to 70 years; The existence of Fissure over 6 weeks; The existence of anal Fissure in physical exam; sign the consent for consciously. The main exclusion criteria: The sensitivities and allergy to the *Myrtus communis* L., Diltiazem and Acetaminophen; anal or rectal surgeries during past 3 months; The inflammatory bowel disease; Immunodeficiency diseases; The history of the illness that needs to use pain-killing drugs continuously; cardiovascular or cerebrovascular diseases; use calcium channel blockers Background of pelvis radiotherapy; Background of main renal, liver, neurologic, hematologic and psychiatry diseases; Background of fecal incontinency; Background of chronic constipation ;pregnancy and breast feeding ;addiction to alcohol and drugs.

Intervention groups

Topical formulation of *Myrtus communis* L. ;on anus
Diltiazem ;three times a day, on anus

Main outcome variables

Discomfort during defecation; anal pain after defecation
;anal bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121031011341N10**

Registration date: **2018-04-16, 1397/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

Registration date

2018-04-16, 1397/01/27

Registrant information

Name

Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a topical formulation of Myrtus communis L. for patients with chronic anal fissure

Public title

Efficacy of a topical formulation of Myrtus communis L. on chronic anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria:the age over 18 years to maximum 70 years;The presence of symptoms of chronic anal fissure (including: bleeding, pain, or both,) for more than 6 weeks;the presence of anal fissure in physical exam;the appearance of horizontal fibers of internal anal sphincter and or sentinel anal tag or hypertrophic papilla;;written informed consent for inclusion.

Exclusion criteria:

Exclusion criteria:sensitivity and allergy to Myrtus communis L. or Diltiazem or Acetaminophen ;anal or rectal surgeries during 12 weeks ago;inflammatory bowel disease;others anal disease including abscess,fistula,moderate or severe eczema around anus or mass(pile);Immunodeficiency diseases;A history of diseases that require continued consumption of analgesics;any cardio-vascular or cerebro-vascular disease;consumption of calcium channel blockers drugs in general or current use of them in treatment of fissure;history of radiotherapy to pelvic region;anal fibrosis or fixed stenosis;history of important renal ,liver,neurologic,hematologic and psychiatry diseases;history of stool incontinency;history of chronic constipation or constipation during 4 weeks ago(2 episodes defecation or less weekly with straining or dense stool passing);pregnancy and lactation;alcohol and opium addiction;inability to cooperate in completing forms(mood disorders or language problems)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization : block Unit of randomization:

individual Tools used in randomization: table of random numbers, sealed envlops, computer softwares How the random sequence was built : The group secretary, based on the number of envelopes (containing letters A and B, respectively, denotes the intervention and control group), identifies the patients for the use of the treatment.Thus, Allocation Concealment is fully observed and the treatment team as well as the statistical analyst are unaware of the allocation of treatment to patients and this process is unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment team, as well as the statistical analyst, are unaware of the allocation of treatment to patients and this process is unpredictable. After the completion of work and statistical analysis of the data are decoded

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Comimtte of Fasa University of Medical Sciences

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Vice Chancellor of Research and Technolog, Fasa University of Medical Sciences, Ebn Sina square, Fasa

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7461686668

Approval date

2016-12-27, 1395/10/07

Ethics committee reference number

IR.FUMS.REC.1395.116

Health conditions studied**1****Description of health condition studied**

Chronic anal Fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal Fissure

Primary outcomes

1

Description

Discomfort during defecation

Timepoint

At the beginning of intervention and every week by phone call

Method of measurement

Visual Analogue Scale

2

Description

Anal pain after defecation

Timepoint

At the beginning of intervention and every week by phone call

Method of measurement

Visual Analogue Scale

3

Description

Anal bleeding

Timepoint

At the beginning of intervention and every week by phone call

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Patient's Global Impression of Improvement (PGI-I)

Timepoint

At the beginning of intervention and every two weeks in person

Method of measurement

Visual Analogue Scale

2

Description

Reepithelialization

Timepoint

At the beginning of intervention and every two weeks in person

Method of measurement

Physical exam

3

Description

Comparison of possible complications of topical formulation of Myrtus communis L. with Diltiazem

Timepoint

Every week by phone call

Method of measurement

Question by check list

4

Description

Comparison of topical formulation of Myrtus communis L. with Diltiazem at amount of acetaminophen consumption.

Timepoint

Every week by phone call

Method of measurement

Based on counting pills

Intervention groups

1

Description

Topical formulation of Myrtus communis L, three times a day on anus

Category

Treatment - Drugs

2

Description

Diltiazem, three times a day on anus

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamzeh Clinic

Full name of responsible person

Dr.Marjan mahmoodi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr.Mojtaba Farjam

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Fasa University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr.Abdolali Pakdaman

Position

Assistant Professor of General surgery

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to
make this available